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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,369	02/26/2004	Shozo Koyama	AMN-006-003	3406
20374	7590	10/06/2006	EXAMINER	
KUBOVCIK & KUBOVCIK SUITE 710 900 17TH STREET NW WASHINGTON, DC 20006			HAQ, SHAFIQL	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/786,369	Applicant(s) KOYAMA ET AL.	
	Examiner Shafiqul Haq	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 29-30 and 40-46, drawn to a method of producing antigenic substance using compound of formula 1-a, classified in class 568 and subclass 303.
- II. Claims 31-32, drawn to a method of producing antigenic substance using compound of formula 1-b, classified in class 568 and subclass 308.
- III. Claims 33-34, drawn to a method of producing antigenic substance using compound of formula 2, classified in class 568 and subclass 317.
- IV. Claims 35-37, drawn to a method of producing antigenic substance using compound of formula 3-a, classified in class 568 and subclass 327.
- V. Claims 38-39, drawn to a method of producing antigenic substance using compound of formula 3-b, classified in class 568 and subclass 328.

The above groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

2. Inventions of group I-V are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, groups I-V require compounds for producing antigenic substance, which are structurally and functionally different. As for example,

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inventions of group I require compound of formula 1-a, which is structurally and functionally different from compound 1-b, which is required by method of group II from producing antigenic substance. Similarly, groups III-V requires compounds (e.g. formula-2, formula 3-a and formula 3-b compound) for producing antigenic substance and each of the compounds are structurally and functionally different.

3. Applicants are advised that an examination on the merits of each of inventions I-VI involves very different patentability considerations. For example, an examination of invention I would require an evaluation of the novelty and unobviousness of the use compound of formula 1-a, while examination of invention III-V would require an assessment of the novelty and unobviousness of the use of compounds of formula 1-b, formula 2, formula 3-a and formula 3-b compounds respectively for producing antigenic substance. The compounds encompassed by the inventions of groups I-V are structurally diverse and dissimilar compounds with different substitution groups and with the present or absent (and position) of double bond in the structure of the compound, wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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5. Claims are generic to multiple patentably distinct species. As for example, compounds of formula 1-a, formula 1-b, formula 2, formula 3-a and formula 3-b compounds are structurally diverse compounds with various possible substitution groups which are structurally and functionally distinct. Compound of formula 1-a has double bond in the ring structure, which is not present in the compound of formula 1-b. Formula 2 compound has dimethyl substitution on ring structure as distinct from compound of formula 1-a or 1-b. Formula 3-a compound has methylene group directly attached to ring structure, which is not present in formula 1-a, 1-b and formula 2 compound. Furthermore, the substitution groups are structurally and functionally distinct and when substituted with combination of structurally different substitution group, would generate a large number of structurally divergent compounds. As for example, halogen atom, amidino group, cycloalkyl group, aralkyl group and alkyl group bonded to aromatic ring selected from benzene, naphthalene and anthracene ring – all are structurally and functionally distinct substitution groups, which do not possess a substantial common core.

Therefore, where an election of any one of Groups I-V is made, an election of a single compound is further required in accordance with the practice set forth in MPEP 803.02 including an exact definition of each substitution on the base molecule, wherein a single member at each substituent group or moiety is selected.

Upon the election of a single disclosed compound, the scope of the invention, inclusive of the elected compound, will be identified by the Examiner for examination

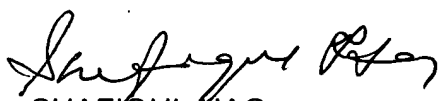
along with the elected species. Moreover, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon. In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound will be determined. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compound are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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6. All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reverse the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 applies with regard to double patenting covering divisional applications.)
7. Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).
8. If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can suggest a group of compounds for examination together, which are similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description. Applicants preserve their right to file a divisional on the non-elected subject matter.
9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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LONG V. LE
SUPERVISORY PATENT EXAMINER
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